FDA OVERSIGHT HEARING ON CODEX BADLY NEEDED

The Honorable Dan Burton, Chairman
House Government Reform and Oversight Committee
c/o Milt Copulos/Beth Clay
Room 2157 RHOB
Washington, DC 20515

3769 '99 SEP 17 P1:06

Dear Congressman Burton:

Prior to last September's meeting of the Codex Committee on Nutrition and Food for Special Dietary Use, you and four other members of Congress strongly requested in writing that the FDA's Dr. Yetley remove the second paragraph from the U.S. codex comments on agenda item #5 (vitamins and minerals), because it contradicted the first paragraph, and lent credence to the unscientific notion that "maximum upper potency limits" should be put on vitamins and minerals. Dr. Yetley not only ignored your written request, but John Hammell caught her doing so on videotape which has been put on the Life Extension Foundation's website in the political section, along with footage of John being forced to stop taping by the German Codex Chairman (http://www.lef.org). A complete account of what happened is available at http://www.iahf.com under "breaking news."

From a standpoint of safety, there is no justification for attempting to apply a "Risk Assessment" document which was designed for evaluating toxic pharmaceutical drugs, to dietary supplements, which have been well established through the National Association of Poison Control Centers, and numerous other sources to be extraordinarily safe, even when consumed in doses much higher than the RDA. Orthomolecular physicians such as Bonnie Camo, M.D. have seen doses as high as 3 grams per day of niacin used in complete safety, while the National Academy of Sciences and FDA are advocating a maximum upper potency limit of just 35 mg, just because a few highly sensitive individuals experience a tingling sensation known as the "niacin flush" when taking niacin in low doses. There is nothing unsafe about the niacin flush, which actually helps circulation and is considered pleasurable by some.

It is obvious to consumers around the world that the FDA is attempting to use the highly unscientific, and heavily prejudiced National Academy of Sciences document titled "A Risk Assessment Model for Establishing Upper Limits for Nutrients" as a means of moving beyond the consumer generated impasse at the Codex Committee on Nutrition and Foods for Special Dietary Use. The FDA has announced its intention to harmonize its regulations to emerging Codex standards in an Advance Notice of Proposed Rulemaking that was published in the Federal Register on July 7, 1997, vol. 62, #129 pp.36243-36248. You can view this at http://iahf.com/codx-fda.txt.

I urge you to call John Hammell, Bonnie Camo M.D., and other witnesses to a Hearing before your Committee, and I urge you to force the FDA to withdraw the second paragraph of its comments along with the NAS Risk Assessment document in keeping with current US Law. Congress has spoken clearly on this with the passage of DSHEA, and most recently again in October of 1997 when dietary supplements were specifically exempted from the harmonization language in the FDA Reform Bill.

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P.S. - Please Read the Attached article. TK

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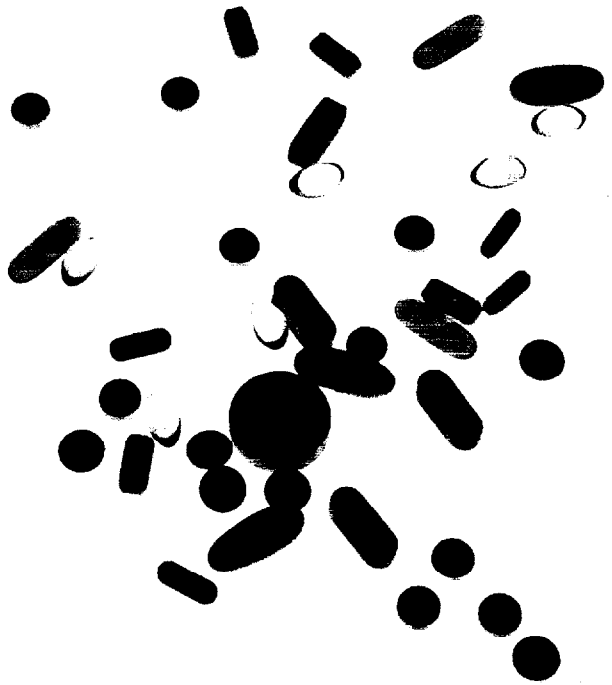
FOCUS

AN URGENT PLEA FOR HELP

Why We Need an Oversight Hearing on CODEX

The shadow of CODEX continues to be a formidable threat to your freedom to buy and use vitamin and mineral supplements.

THIS IS A PERSONAL, AND VERY urgent plea for assistance. I need everyone who reads this to alert more people, and to sign the form letter at the end and send it in to the House Government Reform and Oversight Committee so that we can get an Oversight Hearing in order to hold the FDA accountable for its illegal actions before the CODEX Commission. These actions threaten our access to vitamins and minerals within the therapeutic range, and we must get Bonnie Camo, M.D., and other expert witnesses to appear before a Congressional Oversight Hearing in order to shoot down a very biased National Academy of Sciences "Risk Assessment" document. The FDA illegally put this document before CODEX as part of a desperate effort by the drug cartel to move beyond the consumer generated impasse, which (until now) has been blocking it from its goal of regulating natural products as "drugs." The document corruptly calls for totally unscientific maximum upper potency limits to be put on vitamins and minerals– unless prescribed by an M.D. Our only chance to stop it is through oversight.



I most recently discussed this situation in the January issue of *LIFE EXTENSION* magazine in "Showdown in Berlin," which partially outlined the gross criminal conduct of the FDA at the September 1998 meeting of the UN's Codex Committee on Nutrition and Food for Special Dietary Use. In Berlin, I ambushed Dr. Beth Yetley of the FDA with a camcorder, and caught her violating US law on videotape which has been digitized, and excerpts are currently on the political section of the Life Extension Foundation website at http://www.lef.org. On camera, Yetley blatantly ignored letters from five members of Congress, including Congressman Dan Burton (R-IN), Chairman of the House Government Reform and Oversight Committee, who backed my strong assertion that the FDA must change its comments, and remove a document (NAS) that establishes upper ranges of potency for dietary supplements. We have also uploaded footage that shows the German Chair of the Codex meeting forcing me to turn off my camcorder and cease taping. (The CODEX Commission was very concerned that the public would hear its discussions about banning high potency dietary supplements. They wanted this to be a "closed-door" session, but legally, they had to let me in the door.)

Burton correctly asserted that the FDA's draft comments, combined with the NAS document violated the law, the

will of Congress, and the will of consumers—as clearly expressed in The Dietary Supplement Health and Education Act, and most recently in October of 1997 when through our very hard work at the last minute, we pulled off a miracle by getting dietary supplements specifically exempted from the harmonization language of the FDA Modernization Act of 1997. Clearly, oversight is badly needed to force the FDA to obey the law by withdrawing its comments, along with the NAS document.

Why This is Personal

Twenty years ago, I was forced out of college by suicidal depression and other severely debilitating symptoms. I had been locked up for four years in mental hospitals where they almost killed me with shock treatment and drugs. Not only did I not know how to use nutrients for healing purposes, but they refused to let me try it—denouncing orthomolecular medicine as "unproven." I am living proof that the complex syndrome of biochemical imbalances which the mainstream refers to as "schizophrenia" is completely curable—with vitamins, minerals, amino acids, trace elements, hormones and herbs.

Bonnie Camo, M.D.

While on a pass from the hospital, without their knowledge, I went to an alternative medical clinic called the Princeton Brain Bio Center, where after examining the results of nutritional lab work that the mainstream hospitals didn't know how to do, Bonnie Camo, M.D. was able to look me straight in the eye and explain to me in very simple terms, the biochemical nature of my suffering, and why I must take certain specific nutrients in order to facilitate healing on a cellular level. Her recommendations included taking megadoses of some vitamins, such as 20 grams/day of vitamin C, and 3 grams per day of niacin (vitamin B-3).

Today, Dr.Camo is serving all of us by helping to expose a very biased, totally unscientific paper called "A Risk Assessment Model for Establishing Upper Limits for Nutrients," which was written by the National Academy of Sciences, (NAS) on behalf of the multinational pharmaceutical industry, which is trying to move past a consumer generated impasse at CODEX, which has (until now), been blocking the drug cartel from ramming the German proposal down our throats, threatening to eliminate our access to vitamins and minerals within the therapeutic range—except by prescription. I need your help to ensure that Congress holds an FDA Oversight hearing so that Dr. Camo, and other expert witnesses who are well versed in the healing properties of nutrients, can testify to the fraudulence of the NAS document, as well as the illegality of the FDA's Codex comments.

Even though Congressman Burton is on our side, the pharmaceutical lobby is enormously powerful, and we could easily be denied an oversight hearing unless we swamp the Government Reform and Oversight Committee, and our own Senators and Congressmen with comments. If you have personal concerns that go beyond what I've expressed in my form letter, be sure to either attach them to it or also send in your own letter. The form letter is also available for download on both the LEF and IAHF websites. Dr. Camo has over 20 years of experience in treating patients using vitamins and minerals. She learned under the late Carl C. Pfeiffer, M.D., Ph.D., author of *Mental and Elemental Nutrients*, countless other books and papers and was the founder of the Princeton Brain Bio Center, (which has since closed). Dr. Camo distills the 55 page mine of misinformation in just a few words:

Comments From Dr. Camo

Dr. Camo distills the 55 page mine of misinformation into just a few words.

The Risk Assessment Model (NAS) currently states, "it must be recognized that nutrients possess some properties that distinguish them from the types of agents for which the risk assessment model was originally developed... a fundamental difference between the two categories must be recognized... many [actually all] nutrients are essential for human well being and usually for life itself."

A risk assessment model designed to assess toxicity of drugs and chemicals which are foreign to the body has no relevance to nutrients and other substances that form a normal part of the body. Our metabolic processes have evolved over millions of years using nutrients, such as vitamins, minerals, amino acids, and trace elements, as part of the enzymes that make all chemical reactions in the body happen. Substances which interfere with these reactions, including many pharmaceutical drugs, are potentially toxic. The body has pathways that control absorption, interaction and excretion of nutrients, which it does not have for substances foreign to the body. Foreign substances can be toxic because the body has not evolved mechanisms to control or remove them. Heavy metals such as lead and cadmium can be toxic because they displace essential minerals like zinc from the many enzymes which it activates.

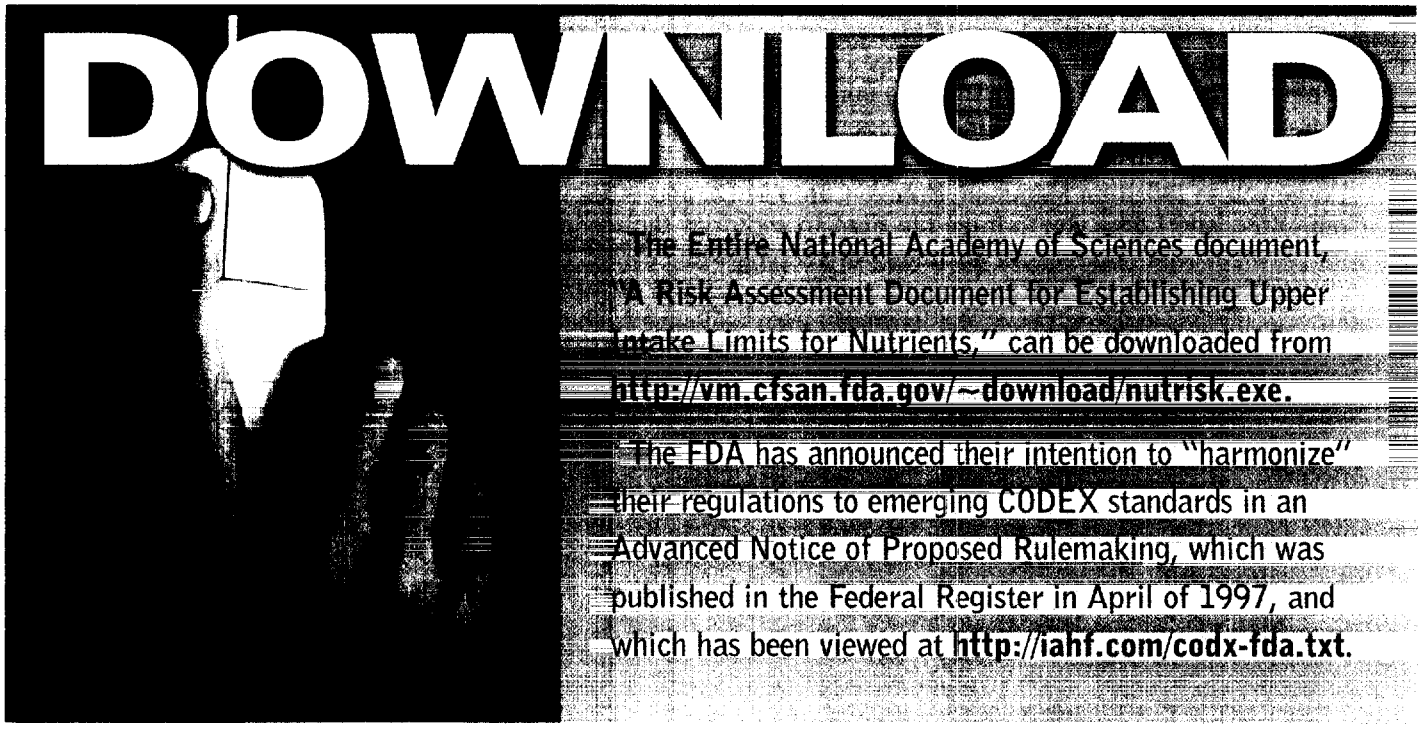
Nutrients are the basis of our metabolism and could not be inherently toxic. How could a body survive if the substances it needed for its metabo-

lism were toxic? The concept of U.L.s based on alleged toxicity of nutrients makes no scientific sense. All nutrients are absolutely necessary to life. Even when taken in large quantities, they are generally without any side effects. Even the rare adverse effects occasionally experienced after taking excessive amounts of nutritional supplements are not generally due to actual toxicities. Taking a large amount of a single nutrient could theoretically create an imbalance among other nutrients, such as by speeding up enzyme systems for which the nutrient is a co-factor. This should at first make the whole system run better as the limiting factor is increased, but could eventually result in increased need for the next most limiting nutrient, producing side effects pointing to the need for additional nutrients. These are not signs of toxicity.

Alleged adverse effects, such as the well known "niacin flush" are not necessarily signs of toxicity. The niacin flush is a sensation of warmth and redness of the skin which may be briefly uncomfortable for some, but is actually enjoyed by others. It is due to dilation of blood vessels by release of histamine, and is actually beneficial to the circulation. Some people take niacin before having sex to increase the natural sex flush described by Masters and Johnson, to enhance orgasm. Niacin (vitamin B-3) also occurs in another form, niacinamide which does not cause a flush. Although the RDA for niacin is only 20 mg., levels of up to 3000 mg per day are prescribed by many conventional physicians for control of cholesterol levels. This is documented in the medical literature. Even higher levels of niacin have been safely and effectively employed for almost fifty years in treatment of psychiatric illness. The first double blind studies ever conducted in the field of psychiatry, in the early 1950's, showed the efficacy and safety of niacin in doses of 3000 mg per day or more, for control of schizophrenia. I have personally, over the past 20 years treated hundreds of mentally ill patients with niacin up to 3000 mg per day without evidence of toxicity. Many patients remain well and out of mental hospitals for years on nutrient therapy. (Editor's note: Anyone taking more than 500 mg of niacin a day for an extended period of time should have a liver enzyme blood test. Some people, especially those with hepatitis C, are especially sensitive to even moderate doses of niacin. Niacin can cause over-acidity in some people's stomachs. Taking buffering agents such as calcium, magnesium or baking soda can help mitigate this potential problem.)

I know of no fatalities attributable to nutritional supplements. The well publicized case of illness and deaths associated with L-tryptophan in the late 1980's was not related to the amino acid itself, but to a contaminant introduced by genetic engineering of the organism that produces it, by Japanese manufacturer Showa Denko.

"It is beyond the scope of the model at this time to address the possible therapeutic benefits of higher nutrient intakes that may offset the risk of adverse effects." But if therapeutic benefits are eventually proven, the limits will have been set too low; people who could have benefitted in the meantime will not, because of the arbitrarily low limits. Biochemical individuality of nutrient requirements may be on the order of one thousand fold, not ten-fold as assumed by the RAM. (p. 26) Basing U.L.s on adverse reactions suffered by the most sensitive members of the population could make it very difficult for other individuals, who may have a much higher requirement, to obtain the levels they need to maintain health, particularly when the adverse events are minor symptoms like flushing, which are not signs of toxicity. —*John C. Hammell*



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